

Application No.: 09/856,933

**REMARKS**

Applicants note that claims 81 and 83 have been allowed. Claim 85 has been amended. Claim 86 has been canceled.

Applicants submitted an amendment on June 7, 2005, which was not entered by the Examiner. The Examiner objected to the proposed amendment to claim 94 and a newly added claim 99 on § 112, first paragraph grounds. In the instant amendment, only claim 85 has been amended and no new claims presented. Applicants respectfully request entry of this amendment and consideration of the arguments presented below.

The Examiner maintained the rejection of claims 84-86 and 93-94 under 35 U.S.C. § 112, first paragraph, as not enabled. Specifically, the Examiner argues that the specification does not teach that the claimed pharmaceutical compositions can be used to effectively treat any autoimmune disease, allergy or tumor disease including AIDS or multiple myeloma. The Examiner does indicate, however, that a pharmaceutical composition comprising a homogenous preparation of recombinant soluble FcγRIIb receptor containing the amino acid sequence of SEQ ID NO: 3 for use in treating multiple sclerosis and rheumatoid arthritis is enabled.

The Examiner correctly notes that the declaration of Dr. Uwe Jacob submitted on January 25, 2005, demonstrates that the claimed pharmaceutical composition can be used in the treatment of multiple sclerosis and rheumatoid arthritis. However, the Examiner overlooks the fact that the declaration also demonstrates the efficacy of the claimed pharmaceutical composition in treating systemic lupus erythematosus (SLE) and alveolitis.

Fc receptors recognize the Fc part of antibodies. Many autoimmune diseases are associated with autoantibodies (antibodies that react against the body's own cells). Since soluble

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Fc receptors are antagonists of cell bound Fc receptors, all autoimmune diseases that are associated with autoantibodies can be treated using the soluble Fc receptor according to the present invention. For example, as disclosed by Dr. Uwe Jacob's previous declaration, several animal models of autoimmune diseases that are associated with autoantibodies have been investigated, i.e, multiple sclerosis, SLE, rheumatoid arthritis and alveolitis. It has been shown that the Fc receptor of the present invention is highly effective in treatment of each of these diseases. Based on these results, one of skill in the art would reasonably conclude that all autoimmune diseases which are associated with autoantibodies can be treated with a pharmaceutical composition comprising the claimed Fc receptor. Claim 85 has been amended to require that the diseases to be treated are characterized by the presence of autoantibodies.

The Examiner also states that the specification is not enabling for the prevention of a disease. Autoantibodies appear long before the autoimmune reaction manifests itself. Furthermore, the presence of autoantibodies often causes complications and, as a result, a poor prognosis for the patient. Since autoantibodies can be easily detected during diagnostic procedures, the Fc receptor of the present invention can be administered as a prophylactic measure to patients with significant autoantibody count in order to prevent the outbreak of the autoimmune disease and to prevent the dangerous complications often associated with the presence of autoantibodies. Thus, Applicants maintain that undue experimentation would not be required with respect to prevention of a disease.

Furthermore, claims 84 and 93 are product claims. Thus, the use to which these products are put is irrelevant as long as it is shown that the products are pharmaceutically effective. The pharmaceutical effectiveness of the compositions of claims 84 and 93 have been adequately established by the specification and the declaration of Dr. Jacob, and the Examiner has even

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stated so. Thus, the enablement rejection with respect to these claims should be withdrawn.

All rejections have been addressed and should be withdrawn. Applicants respectfully request allowance of this application.

A fee of \$60.00 for a one month extension of time is due with this filing. Please charge this fee to Deposit Account No. 50-0624, under Order No. NY-HUBR 1189-US, from which the undersigned is authorized to draw.

Dated: August 2, 2005

Respectfully submitted,

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